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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,711	02/03/2004	Jeffrey Young	USP2259A-JEF	4135

30265 7590 04/24/2006

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,711	YOUNG, JEFFREY	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *7,8 and 26-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *February 2, 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, Claims 1-6 and 9-25, in the reply filed on February 10, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-6 and 9-25 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 9-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said living object" in line 2. There is a lack of clear antecedent basis for this limitation in the claim.

The metes and bounds of Claims 7 and 8 are rendered uncertain by the terms "Panulownia" and "Glubularia" because a thorough search of both patent and non-patent literature did not result in a finding of the claim-designated plant genera. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. Please note that the

specification, as well as the claims, recites these terms. Appropriate correction is required.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claim 1, line 1, is objected to for the following informality: After "treating", the claim recites "of". Applicant should delete "of" to place the claim in proper grammatical form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 and 9-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (N).

Applicant claims a method of treating a living subject with non-insulin dependent diabetes mellitus comprising a step of administering to said living subject a composition comprising a berberine as a first active ingredient and a catalpol as a second active

ingredient. Applicant further claims the method, as recited in claim 1, wherein the composition further comprises an oleanolic acid as a third active ingredient; wherein the berberine is obtained from one or more natural herbs selected from the group consisting of Berberis, Chelidonium, Stephniz, Coptis, Phellodendron and Ziziphus; wherein the composition is prepared into a predetermined form for administration that contains 1 to 300 mg/dg/dl of the berberine; and, wherein the composition is prepared into a predetermined form for administration that contains 1 to 300 mg/dg/dl of the active ingredients. Applicant further claims the method, as recited in claim 3, wherein the catalpol is obtained from one or more natural herbs selected from the group consisting of Rehmannia, Verbascum, Panulownia, Glubularia and Adonis; wherein the composition is prepared into a predetermined form for administration that contains 1 to 300 mg/dg/dl of the berberine; and, wherein the composition is prepared into a predetermined form for administration that contains 5 to 150 mg/dg/dl of the berberine. Applicant further claims the method, as recited in claim 2, wherein the oleanolic acid is obtained from one or more natural herbs selected from the group consisting of Olea, Swertia, Astrantia, Lonicera and Beta; and, wherein the composition is prepared into a predetermined form for administration that contains 1 to 300 mg/dg/dl of the ingredients. Applicant further claims, the method as recited in claim 5, wherein the berberine is obtained from one or more natural herbs selected from the group consisting of Berberis, Chelidonium, Stephniz, Coptis, Phellodendron and Ziziphus and the catalpol is obtained from one or more natural herbs selected from the group consisting of Rehmannia, Verbascum, Panulownia, Glubularia and Adonis. Applicant further claims the method,

as recited in claim 3, wherein the composition is prepared as either a draught in water, a syrup, a cachet, tablet or solution.

Li teaches a sugar-lowering tablet comprising each of the claim-designated natural herb ingredients of Phellodendron (a berberine ingredient), Rehmannia (a catapol ingredient), figwort or Scrophularia (a catapol ingredient) and honeysuckle or Lonicera (an oleanolic acid ingredient), which can also be used in the making of a food product. Li is silent to the active ingredients contained therein the referenced composition. However, given that Li teaches that the referenced tablet has blood sugar lowering effect and is useful for treating diabetes; and given that Li teaches a composition comprising each of the claim-designated natural herb ingredients of Phellodendron, Rehmannia and Lonicera which are known to be sources of each of the three active ingredients (as evidenced by the claims themselves and as readily admitted by Applicant), the Office deems that the instantly claimed active ingredients of berberine, catapol and oleanolic acid, as well as the claim-designated predetermined amounts of the active ingredients, are inherent to the composition taught by Li, absent evidence to the contrary.

The teachings of Li are set forth above. Li teaches the instantly claimed invention except for a method of treating a living subject with non-insulin diabetes mellitus comprising administering the referenced composition to a living subject in need thereof, wherein the referenced composition comprises berberine as a first active ingredient, catapol as a second active ingredient, and further comprising oleanolic acid as a third active ingredient in predetermined amounts as instantly claimed by Applicant.

However, it would have been obvious to one of ordinary skill in the art and one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to administer the composition taught by Li to a living subject in need thereof to provide the instantly claimed method of treating non-insulin diabetes mellitus in a living subject in need thereof because at the time the invention was made Li taught, "The invented product possesses obvious effect for reducing blood sugar, and is non-toxic, doesn't result in hypoglycemia, and can be used for curing diabetes, heart diseases, hypertension and hyperlipemia, *etc.*"

With regard to the claim limitations of each of Claims 1-16 wherein Applicant directs the instantly claimed method to a composition prepared as either a draught in water, a syrup, a cachet and a solution, it would have been *prima facie* obvious to one of ordinary skill in the art practicing the invention to modify the form of the composition taught by preparing the composition as either a draught in water, a syrup, a cachet or a solution to provide the instantly claimed method because at the time the invention was made each of the claim-designated pharmaceutical forms were known to be conventional and useful vehicles for the delivery of an anti-diabetic agent for the treatment of non-insulin diabetes mellitus, especially since Li taught that the referenced sugar-lowering tablet could be incorporated into other pharmaceutical vehicle forms, such as a food for the delivery of the composition to provide a sugar lowering effect. Accordingly, the claimed invention as a whole was *prima facie* obvious, given the teachings of Li, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 1-6 and 9-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (N) in view of Song et al. (U), Jiang et al. (O), Wang et al. (V), Chen et al. (W), Hsu et al. (X), Takahashi (A*), Grayer-Barkmeijer (U1), Yoshikawa et al. (V1), Somava et al. (W1), Li et al. (O) and Prasad et al. (X1).

Applicant's claimed invention was set forth above.

The obvious teachings of Li, absent evidence to the contrary, teach a method of treating a living subject with non-insulin dependent diabetes mellitus comprising a step of administration to a living subject a composition comprising a berberine as a first active ingredient and a catalpol as a second active ingredient and an oleanolic acid as a third active ingredient. As set forth while, the obvious method of use for the anti-diabetic composition taught by Li does not expressly teach a method of treating non-insulin dependent diabetes mellitus in a subject in need thereof comprising the administration of the instantly claimed ingredients of berberine, catalpol, and oleanolic acid. However, in the alternative, even if the claimed method of treatment is not identical to the obvious method of treatment taught by Li, the difference that which is disclosed and that which is claimed are considered to be so slight that the obvious method of treatment is likely to inherently possess the same characteristics of the claimed method in view of the similar characteristics which they have been shown to share. Thus, the method comprising the administration of the claim-designated ingredients from the claim-designated natural herbs would have been obvious to those of ordinary skill in the art within the meaning of USC 103. For instance, while Li expressly teaches a blood sugar-lowering composition comprising Phellodendron,

Rehmannia, figwort or Scrophularia and honeysuckle or Lonicera; and, while it is known in the art of chemistry that the plants comprising the Li' composition are good sources for berberine, catapol or oleanolic acid, Li does not expressly teach that the referenced composition comprises each of the claim-designated ingredients. However, it would have been obvious to one of ordinary skill in the art to optimize the composition used in the obvious method of treatment taught by Li by providing predetermined dosage amounts of the claim-designated ingredients to provide the instantly claimed method because at the time the invention was made because Song, Jiang and Chen taught methods of treating non-insulin diabetes mellitus comprising the administration of an effective amount of berberine to a living subject in need thereof and Prasad taught Phellodendron as a source of berberine and Chen taught Coptis as a source of berberine; each of Hsu and Takahasi taught a method of treating non-insulin diabetes mellitus comprising the administration of an effective amount of an extract comprising Rehmanniae to a living subject in need thereof and that Rehmanniae comprises catapol; and, Grayer-Barkmeijer taught that the plant genera of Scrophularia (Rehmanniae), Verbascum and Globularia are sources of catapol; and, each of Yoshikawa, Somava and Li taught methods of treating diabetes mellitus in a living subject comprising the administration of effective amounts of a composition comprising an oleanolic acid obtained from beets (Yoshikawa) and Olea (Somava); and Prasad taught that Lonicera (honeysuckle) is a source of oleanolic acid. At the time the invention was made, one of ordinary skill in the art would have been motivated one would have had a reasonable expectation of success to optimize the composition used.

in the obvious method of treatment taught by Li by providing predetermined dosage amounts of the claim-designated ingredients to provide the instantly claimed method because at the time the invention was made the prior art taught that berberine, catalpol and oleanolic acid are useful in the treatment of non-insulin dependent mellitus and each of the claim-designated ingredient natural herbs have been found useful as sources of the claim-designated active ingredients and/or useful in the making of compositions exhibiting anti-diabetic effects and intended for the purpose of use in treating living subjects with diabetes mellitus.

Thus, given the obviated method of treating non-insulin dependent diabetes mellitus in a subject comprising the administration of the composition taught by Li and given that the prior art taught that each of berberine, catapol and oleanolic acid are useful ingredients for the making of a therapeutic pharmaceutical composition for the treatment of the claim-designated disease condition and given that the prior art teaches that the claim-designated natural herbs are useful sources of berberine, catapol and oleanolic acid such as the Phellodendron, Rehmanniae and Lonicera comprising the composition taught by Li, the instantly claimed method would have been *prima facie* obvious to one of ordinary skill in the art to optimize the chemical constituents comprising the blood sugar lowering tablet taught by Li and the amounts contained therein to provide an effect result variable to provide a method of treating diabetes mellitus, especially in view of the prior art that teaches that the anti-diabetic functional effect of each of the claim-designated active ingredients are dose dependent. Thus, the instantly claimed invention would have been no more than the addition and/or the

replacement of any of the berberine-, catapol- and/or oleanolic acid-containing natural herbs comprising the composition taught by the prior art as being useful in the making of an anti-diabetic composition, each functional equivalent for the other since the prior art taught the beneficial functional effect of natural herbs comprising the claim-designated ingredients in the making of compositions for use in treating living subjects with diabetes mellitus.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed method because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, at the time the invention was one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claimed ingredients taught by the prior art as being obtainable from the claim-designated natural herbs and having anti-diabetic activity to provide the claimed method because the claimed invention is no more than the combining of well known ingredients used in well known methods for treating living subjects with non-insulin dependent diabetes mellitus.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations, as well as the experimental parameters for the manufacturing thereof, are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references to provide the instantly claimed method of treatment.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele Flood
Primary Examiner
Art Unit 1655

MCF
April 15, 2006

MICHELE FLOOD
PRIMARY EXAMINER